FEB - 2 2012

MED-TEK
MEDICAL TECHNOLOGIES UNLIMITED

510(k) Summary for K113074

Medical Technologies Unlimited, Inc. (MED-TEK)

Comprehensive Muscular Activity Profiler Pro (CMAP Pro™)

1. Submitter Information

Submitter's Name and Address:

Medical Technologies Unlimited, Inc. (Med-Tek)
2665 S. Bayshore Drive #502
Coconut Grove, FL 33133

Submitter's Telephone and fax numbers:

Phone: 866-930-2627
Fax: 866-980-2627

Contact Person:
Marco Vitiello, M.D. Medical Director
Medical Technologies Unlimited, Inc. (Med-Tek)
2665 S. Bayshore Drive #502
Coconut Grove, FL 33133

Date this 510(k) summary was prepared:
January 9, 2012.

2. General Device Information

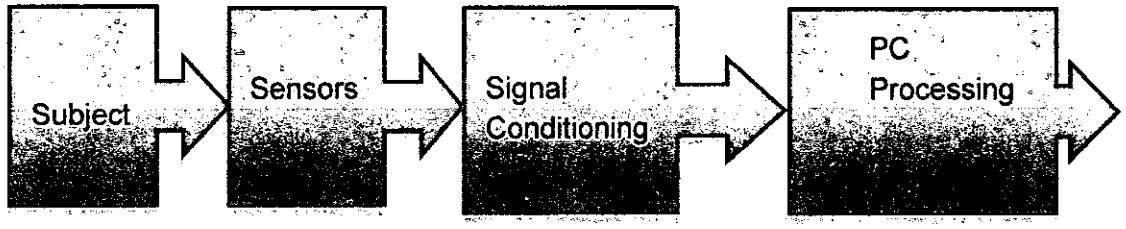
Trade Name of Device: Comprehensive Muscular Activity Profiler Pro (CMAP Pro™)
Classification Name: Diagnostic Electromyograph (21 CFR 890.1375)

Predicate Device: Medical Technologies Unlimited Comprehensive Neuromuscular Profiler (CNMP)
Predicate Device 510(k) number K031995

3. Device Description:

The CMAP Pro™ is a stand-alone, battery operated dynamic muscle function monitoring system, with a number of surface electromyography (sEMG) sensors connected to various parts of the subject's body for data collection. The data are then directly fed into a system for conditioning, acquiring, and transmitting sensor data. Analyzed signals include sEMG readings, motion detection, and muscle strength measurements. The system acquires continuous analog signals and then digitizes these signals by sampling at a rate of 2kHz. These data are then transferred wirelessly to an all-in-one PC for processing using software.. The system is capable of monitoring and video recording data from (sEMG) sensors

connected to various muscle groups in the human body. During the acquisition of sEMG signals, the system will simultaneously acquire motion tracking of the body, isometric functional testing and pinch and grip strength measuring.



4. Intended Use of Device:

The CMAP Pro is indicated for surface electromyography with video recording, range of motion tracking, isometric functional testing and pinch and grip strength measuring.

5. Comparison to Predicate Device:

The CMAP Pro and the predicate systems, our CNMP, both use a range of motion device in combination with functional capacity evaluation devices and surface EMG electrodes to obtain similar data. Instead of the electromagnetic field-based range-of-motion unit of the predicate device, the CMAP Pro uses gyroscopic sensors to detect motion. Instead of the 3 off-the-shelf functional capacity evaluation devices of the predicate system, the CMAP Pro uses a Med-Tek proprietary, integrated functional capacity evaluation (FCE) sensor. Both devices utilize surface EMG electrodes. The signal conditioning in the CMAP Pro takes place in two stages, one outside the POD and close to the sEMG sensor leads and the other inside the POD itself. In the predicate device, all signal conditioning took place inside the main unit. The CMAP Pro POD is smaller and thinner than the predicate, and it is battery powered rather than AC powered. The CMAP Pro transmits all data wirelessly via an ad hoc wireless network while the predicate device transmits data via USB 2.0.

6. Performance Testing:

The CMAP Pro complies with IEC 60601-2-40 and all applicable performance tests in that standard. Additionally, validation tests were performed to validate the accuracy and repeatability of the range of motion (ROM) sensors, the FCE sensor, and the EMG leads. It was shown through the validation tests that the ROM sensors, FCE sensor, and EMG test leads captured data accurately and repeatably.

In conclusion, the functionality of the new device is identical to the predicate device from a black box perspective. The underlying technology enhancements used to collect data using the range of motion (ROM) sensors, the FCE sensor, and the EMG leads are transparent to the user in terms of device functionality.Therefore the device is as safe, as effective, and performs the same as our predicate device and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medical Technologies Unlimited, Inc.
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, New York 11747

FEB -2 2012

Re: K113074
Trade/Device Name: CMAP Pro
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: IKN
Dated: January 17, 2012
Received: January 18, 2012

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Statement of Indications for Use

510(k) Number (if known): K113074

Device Name: CMAP Pro

Indications for Use:

Surface electromyography with video recording, range of motion tracking, isometric functional testing and pinch and grip strength measuring.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113074